

Pesticide Steering Committee
Minutes of the 15th meeting
Held on 11 – 12 June 2013, Parma

(Agreed on 18 02 2014)¹

Participants

- Network Representatives of Member States:**

Country	Name ²	Country	Name
Austria	Robert Womastek	Latvia	Dace Bumane
Belgium	Philippe Castelain	Lithuania	Kristina Valioniene
Bulgaria	Iva Romanova	Netherlands	Nanda Bezem
Czech Republic	Martin Prokop	Poland	Robert Bańkowski
Estonia	Jan-Roland Raukas	Portugal	Bento De Carvalho
Germany	Herbert Köpp	Spain	Carmen López Goti
Hungary	Tamás Griff	Sweden	Sylvia Karlsson
Ireland	Dermot Sheridan	United Kingdom	Steve Dobson

- Panel Members**
None
- Hearing Experts**
None
- European Commission and/or Member States representatives:**
 - Wolfgang Reinert (DG SANCO)
- EFSA:**
 - Pesticides Unit (Herman Fontier, Head of Unit)
 - Pesticides Unit (Luc Mohimont, Deputy Head of Unit)
 - Pesticides Unit (Jane Barling, Coordination Team)
 - Pesticides Unit (Jürgen Sturma, Coordination Team)

¹ The publication of the minutes shall be made without delay in compliance with the Founding Regulation and no later than 15 working days following the day of their agreement.

² Indicate first full name and then surname (John Smith) all throughout the document

- Pesticides Unit (Christopher Lythgo, Fate and Behaviour Team)
- Pesticides Unit (Oriol Magrans, Fate and Behaviour Team)
- Applications Desk Unit (Karine Lheureux, Head of Unit)
- Applications Desk Unit (Tom Meyvis, scientific officer)
- **Others (if applicable such as WGs/other country representatives)**
 - Pelin Aksu (Turkey)
 - Sanja Miloš (Croatia)
 - Nedeljko Latinović (Montenegro)
 - Fikret Ajdini (Former Yugoslav Republic of Macedonia)
 - Lucia Klauser (Switzerland)
 - Stefania Barmaz (ECHA)

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (Dols)³ and the Decision of the Executive Director implementing this Policy⁴, members of networks, peer review meetings, networking meetings and their alternates shall be invited to complete and submit an Annual Declaration of interest (ADol).

EFSA screened the ADol filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest (ODol) at the beginning of this meeting.

The Chair thanked the representative(s) that has/have submitted an ADol and/or has/have declared some interest at the beginning of this meeting in the ODol.

4. Agreement of the minutes of the 14th meeting of the Pesticide Steering Committee held on 16 – 17 October 2012, Parma.

The minutes were agreed.

Follow up on:

- point 6: COM has developed an overview table of new active substances applied for under Regulation (EC) No 1107/2009, which is available on CIRCABC.

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

- point 13: progress has been made with regard to the template for the list of endpoints, as reported by EFSA at point 14 of the agenda.

5. Topics for discussion

5.1 Work programme for new a.s.

The RMSs gave an update on the status of the work programme for the new active substances under evaluation in accordance with the procedure laid down in Regulation (EC) No 1107/2009.

5.2 EFSA Applications Desk

Presentation from EFSA. The RMSs are kindly asked to provide the justification form together with the sanitised (supplementary) summary dossier, which should be made available as a stand alone document. The Applications Desk is currently preparing instructions for applicants on these issues and MSs were invited to provide comments on the draft text.

It was agreed that RMSs should upload DARs to the EFSA extranet as pdf-files, which should be named according to the naming convention.

EFSA prefers to distribute the DARs only through the EFSA extranet, however, since MSs and COM highlighted the need to have all documents related to an active substance in one place, it was agreed to continue uploading the DARs on CIRCABC.

Action point:

MSs are invited to submit comments to the Applications Desk on the draft instructions for applicants by 17 June 2013 (APDESK.applications@efsa.europa.eu).

5.3 Classification and labelling

Update on sulfoxaflor

The RMS (IE) gave an update on the status of the peer review for sulfoxaflor.

Presentation by ECHA

ECHA gave a presentation on the CLH process for active substances in plant protection products and further proposals for alignment of the CLH and approvals processes. For planning purposes, and to better facilitate the possible alignment of the processes, Member State competent authorities are asked to provide early information on their planned CLH dossier submissions via the ECHA registry of intentions. ECHA is exploring ways in which it can further support dossier submitters in the pre-submission phase, and is also reviewing the CLH report format in consideration of the DAR format and possible options for better alignment of the documents.

Prioritisation of substances for the classification process

The UK gave a short presentation on a scheme it has developed setting out a possible way forward for the prioritisation of substances for classification. MSs are invited to submit comments on the proposal for further discussion at a future meeting of the PSC.

Action point:

EFSA to make the draft documents available via the EFSA extranet.

MSs are invited to submit comments via EFSA by mid-September 2013 (pesticides.peerreview@efsa.europa.eu).

5.4 Applications to amend approval conditions

DE gave a short presentation on various issues that have been raised following the experience gained with the first applications for amendment of the conditions of approval considered in accordance with the procedure laid down in Regulation (EC) No 1107/2009. It was agreed that it would be useful for COM to provide clarifications in the format of a guidance document for this procedure, taking into consideration comments and proposals from the MSs and EFSA, for further discussion at the next PSC meeting.

Action point:

MSs and EFSA are invited to submit comments and proposals to COM (Wolfgang Reinert) by 31 August 2013.

5.5 EFSA SOP GLP

Presentation by EFSA. In 2011 and 2012 EFSA requested the GLP monitoring authorities to perform an audit on a number of GLP studies received by EFSA. Subsequently a need was identified for an internal EFSA SOP to be developed setting out the criteria to be used for the selection of studies for audit, and the procedure for evaluation of the study audit reports and follow-up actions. The draft SOP was discussed with the GLP monitoring authorities in early 2013 and is expected to be finalised by mid-2013.

5.6 Guidance documents

Update on the development process of Guidance Documents

EFSA gave an overview of the situation regarding the development of guidance documents, and of the related outsourced activities.

Improving the accessibility of guidance documents

MSs expressed the need for a general document on procedures applicable to the development of guidance documents in order to improve the transparency of this process and the engagement of stakeholders. MSs suggested EFSA to consider creating a specific area on the EFSA website on this matter. EFSA will reflect further on this issue. COM advised that the planned guidance document on guidance documents will not be progressed. EFSA will reflect further on this issue. COM advised that the planned guidance document on guidance documents will not be progressed.

5.7 Modelling/Q10 – guidance on applying new models for DARs on new active substances

It was noted that in the case of new active substances considered in accordance with Regulation (EC) No 1107/2009 the guidance documents available at the time of application are applicable (Article 12(2) refers).

With regard to the new active substances considered in accordance with Commission Regulation (EU) No 188/2011, it was noted that it was previously discussed and agreed by the PSC in their 10th meeting in November/December 2010 that the latest guidance should apply, with the exception of the guidance document for birds and mammals and any new guidance adopted during the course of the peer review.

In the case of AIR II substances, it was noted that, in accordance with paragraph 4.2 of COM's guidance document on the renewal of active substances to be assessed in compliance with Commission Regulation (EC) No 1141/2010 (SANCO/10387/2010

rev.8 refers), the guidance available at the time of entry into force of the Regulation is applicable.

5.8 Terms of reference of the PSC

Presentation from EFSA. EFSA has undertaken a self review of the EFSA Scientific Networks, based on consultations with Advisory Forum members and Network members. A number of recommendations have been made as a result of the review, including the following:

- The Terms of Reference for the Networks should be reviewed regularly and at least every 3 years;
- The names of all Networks should be harmonised;
- MS representatives in the Networks should commit to liaise as appropriate at national level before and after each Network meeting, and that this commitment should be formalised by including it in the Terms of Reference of the Network.

The members agreed to include the latter point in the Terms of Reference, which do not need any further review. Further consideration will be given to the need to re-name the PSC.

Action point:

EFSA to update the Terms of Reference and to further consider the need to re-name the Network.

5.9 Work Programme AIR II

The RMSs gave an update on the status of the work programme for the renewal of approval of active substances under evaluation in accordance with the procedure laid down in Commission Regulation (EC) No 1141/2010. MSs were invited to share their experience gained in considering the AIR II substances with a view to developing a 'lessons learned' paper in preparation for the AIR III programme. It was agreed that it would be useful to have a more thorough exchange at the next PSC meeting.

Action point:

MSs are invited to submit topics for discussion and feedback arising from the AIR II evaluations to EFSA by the end of September 2013
(pesticides.peerreview@efsa.europa.eu).

5.10 Update on grants and procurements

EFSA gave an update on the recently finalised, ongoing and planned outsourcing projects, including a more detailed update on the provisional results of the grant with regard to the EFSA Guidance on scientific peer reviewed open literature.

5.11 New template for the list of endpoints

As follow-up to the action point identified for EFSA at point 13 of the previous PSC meeting in October 2012, EFSA advised that the current template for the list of endpoints has been discussed and updated in the expert meetings scheduled in the first half of 2013 (i.e. in the sections on mammalian toxicology, fate and behaviour and ecotoxicology). Written consultations have taken place/will take place in the sections on residues and phys-chem properties.

In addition, COM asked EFSA to initiate a revision of the template in light of the new data requirements, and consultations took place in the fate and behaviour and mammalian toxicology expert meetings. Written consultations in the other sections will take place in June-July, following which EFSA will finalise the draft template. The

UK agreed to support the development of the new template by providing a proposal to address the necessary endpoints for efficacy.

It was agreed that the draft templates would be submitted to the PSC members for a final consultation before submission to COM for taking note at the Standing Committee on the Food Chain and Animal Health.

Action points:

- EFSA to distribute to MSs a proposal for an update to the current template in the area of residues by mid-June for consultation and comments.
- EFSA to distribute to MSs a proposal for a new template in light of the new data requirements in the areas of residues and ecotoxicology by mid-June for consultation and comments.
- MSs are invited to provide comments on the proposals by mid-July (pesticides.peerreview@efsa.europa.eu).
- The UK is invited to submit proposals in relation to the necessary efficacy endpoints to EFSA by the end of July (pesticides.peerreview@efsa.europa.eu).

EFSA to finalise the updated current template and the new template by end of July for submission to the PSC members for final comments before submission to COM.

5.12 Data access policy

Not discussed. This item was considered to be of more relevance to the EFSA Networking Group on Pesticide Monitoring.

5.13 Long range transport of a.s.

Presentation from EFSA. It was discussed whether there is a need to revise the current approach with regard to the identification of a critical area of concern in relation to the issue of long range transport in light of the related criteria set out in Annex II of Regulation (EC) No 1107/2009.

Action point:

MSs are invited to consider EFSA's proposal to update the approach and submit comments by the end of July 2013 (pesticides.peerreview@efsa.europa.eu).

6. Next meeting

26th – 27th November 2013.